

UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF TEXAS

MELVIN ABROTSKY,
STEVEN NELS ASLIN,
WILLIAM PAUL BARNETT,
STANLEY WAYNE BAZEMORE,
JOSEPH F. BEVILACQUA,
SANDRA CHRISTINA BLACK,
CONNIE G. BOWLING,
JAMES EDWARD BROADWAY,
MILTON BULLARD, JR.,
JOHN P. CACHIOLI,
DAVID J. CARIAGA,
DAMASE A. CARON,
CHARLES RAY COLE,
ROBERT B. COLINI,
SCOTT F. CROMARTY,
WAYNE R. CUMMINGS, SR.,
MACK W. DUKES, JR.,
RODNEY W. EARWOOD,
MICHAEL P. EMMONS,
CEPHAS D. ERTZBERGER,
ROBERT F. FEIBUSCH,
BARBARA FRANCES GARCIA,
GEORGE EMMA GLASS,
EMMA J. GOLDEN,
BEATRICE GORDON,
CONNIE LEE HARMON,
BARBARA ANN HARVEY,
EMERSON HICKLIN,
ROBERT PATRICK HURLEY,
GENEVA JACKSON-MILLS,
MICHAEL J. KARATY, JR.,
JAMES FREEMAN KING,
JACK W. KRUSE,
JOHN A. KUZEMKA,
ROSE A. LOWE,
VERNON EUGENE MEASELS,
GARY DANA MESSMAN,
CHARLES M. MOORE,
KENNETH BERNARD MOORE,
GALE J. MORROW,
EARTHA MAE NOBLES,

CASE NO: _____

CIVIL ACTION COMPLAINT
AND JURY TRIAL DEMAND

LARRY RILEY OWENS,	§
RALPH LEONARD PAYNE,	§
ALICE N. PIPER,	§
ROGER EDWARD QUILLINGS,	§
ELBERT B. RANDOLPH,	§
GEORGE THOMAS REAGAN, JR.,	§
JAMES D. REYNOLDS,	§
RUSSELL ROBERT RICHEY,	§
ANGELITA RODRIGUEZ,	§
FRED D. SALL,	§
JAMES R. SEYBOLD,	§
ALVESTER SHEFFIELD, JR.,	§
CHARLES WESLEY SMITH,	§
MICHAEL LAYVONNE SPARKS,	§
ALLEN E. STARKE,	§
REUBEN W. STEWART,	§
MARSHA LYNN STUDLE,	§
BARBARA A. TAYLOR,	§
DENNY L. TAYLOR,	§
GERALDINE MARIE TAYLOR-	§
BROWN,	§
KENNETH IAN TRAVIS, SR.,	§
LEONARD WENGROW,	§
ROBERT A. WILDER,	§
RANDALL SCOTT WILLIAMS, and	§
DAVE WILSON,	§
 Plaintiffs,	§
 v.	§
 MEDTRONIC, INC., MEDTRONIC	§
INTERNATIONAL TECHNOLOGY,	§
INC., and MEDTRONIC PUERTO	§
RICO OPERATIONS CO.,	§
 Defendants.	§

COMPLAINT

Plaintiffs, MELVIN ABROTSKY, STEVEN NELS ASLIN, WILLIAM PAUL BARNETT,
STANLEY WAYNE BAZEMORE, JOSEPH F. BEVILACQUA, SANDRA CHRISTINA BLACK,
CONNIE G. BOWLING, JAMES EDWARD BROADWAY, MILTON BULLARD, JR., JOHN P.

CACHIOLI, DAVID J. CARIAGA, DAMASE A. CARON, CHARLES RAY COLE, ROBERT B. COLINI, SCOTT F. CROMARTY, WAYNE R. CUMMINGS, SR., MACK W. DUKES, JR., RODNEY W. EARWOOD, MICHAEL P. EMMONS, CEPHAS D. ERTZBERGER, ROBERT F. FEIBUSCH, BARBARA FRANCES GARCIA, GEORGE EMMA GLASS, EMMA J. GOLDEN, BEATRICE GORDON, CONNIE LEE HARMON, BARBARA ANN HARVEY, EMERSON HICKLIN, ROBERT PATRICK HURLEY, GENEVA JACKSON-MILLS, MICHAEL J. KARATY, JR., JAMES FREEMAN KING, JACK W. KRUSE, JOHN A. KUZEMKA, ROSE A. LOWE, VERNON EUGENE MEASELS, GARY DANA MESSMAN, CHARLES M. MOORE, KENNETH BERNARD MOORE, GALE J. MORROW, EARTHA MAE NOBLES, LARRY RILEY OWENS, RALPH LEONARD PAYNE, ALICE N. PIPER, ROGER EDWARD QUILLINGS, ELBERT B. RANDOLPH, GEORGE THOMAS REAGAN, JR., JAMES D. REYNOLDS, RUSSELL ROBERT RICHEY, ANGELITA RODRIGUEZ, FRED D. SALL, JAMES R. SEYBOLD, ALVESTER SHEFFIELD, JR., CHARLES WESLEY SMITH, MICHAEL LAYVONNE SPARKS, ALLEN E. STARKE, REUBEN W. STEWART, MARSHA LYNN STUDLE, BARBARA A. TAYLOR, DENNY L. TAYLOR, GERALDINE MARIE TAYLOR-BROWN, KENNETH IAN TRAVIS, SR., LEONARD WENGROW, ROBERT A. WILDER, RANDALL SCOTT WILLIAMS, and DAVE WILSON, by their undersigned counsel, hereby commence their individual actions against Medtronic, Inc., Medtronic International Technology, Inc., and Medtronic Puerto Rico Operations Co. (hereinafter collectively "Defendants" or "Medtronic," unless otherwise stated) for compensatory, equitable, injunctive, and declaratory relief. Plaintiffs make the following allegations based upon their personal knowledge as to their acts and upon information and belief which has evidentiary support now or is likely to have evidentiary support after a reasonable opportunity for further investigation or discovery, and allege as follows:

I. JURISDICTION AND VENUE

1. This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1332(a) because the parties are citizens of different States and the matter in controversy exceeds the jurisdictional amount exclusive of interest and costs.
2. Venue is proper pursuant to 28 U.S.C. §§ 1391(a) and (c). The Court has personal jurisdiction over Defendants, because they have done and continue to do business in this State, have committed a tort, in whole or in part, in this State and have continuing contacts in this State. At all relevant times and concurrently hereto, Defendants have continuously conducted business in this State and this particular venue by marketing, distributing and selling its defective Sprint Fidelis Leads. The exercise of jurisdiction over Defendants will not offend traditional notions of fair play and substantial justice. Venue is proper under 28 U.S.C. § 1391(c) because these Defendants are corporations and are deemed to reside within any judicial district in which they are subject to personal jurisdiction.

II. PARTIES

- 3.1. Plaintiff, MELVIN ABROTSKY, is an individual and citizen of the County of Broward, State of Florida, and resides at 9837 Northwest 2nd Court, Plantation, Florida 33324.
- 3.2. Plaintiff, STEVEN NELS ASLIN, is an individual and citizen of the County of Lake, State of Florida, and resides at 2942 Sunrise Road, Lady Lake, Florida 32159.
- 3.3. Plaintiff, WILLIAM PAUL BARNETT, is an individual and citizen of the County of Broward, State of Florida, and resides at 600 North 17th Avenue, Hollywood, Florida 33020.
- 3.4. Plaintiff, STANLEY WAYNE BAZEMORE, is an individual and citizen of the County of Screven, State of Georgia, and resides at 479 Bazemore Loop, Sylvania, Georgia 30467.
- 3.5. Plaintiff, JOSEPH F. BEVILACQUA, is an individual and citizen of the County of Pinellas,

State of Florida, and resides at 34679 Maple Drive, Pinellas Park, Florida 33781.

- 3.6. Plaintiff, SANDRA CHRISTINA BLACK, is an individual and citizen of the County of Marion, State of Florida, and resides at 668 Northeast 128th Avenue, Silver Springs, Florida 34488.
- 3.7. Plaintiff, CONNIE G. BOWLING, is an individual and citizen of the County of Madison, State of Florida, and resides at 933 Northeast Nixon Loop, Madison, Florida 32340.
- 3.8. Plaintiff, JAMES EDWARD BROADWAY, is an individual and citizen of the County of Hillsborough, State of Florida, and resides at 2508 River Briar Boulevard, Ruskin, Florida 33570.
- 3.9. Plaintiff, MILTON BULLARD, JR., is an individual and citizen of the County of Duval, State of Florida, and resides at 7662 Fawn Lake Drive South, Jacksonville, Florida 32256.
- 3.10. Plaintiff, JOHN P. CACHIOLI, is an individual and citizen of the County of Pasco, State of Florida, and resides at 10504 Tapestry Drive, Port Richey, Florida 34668.
- 3.11. Plaintiff, DAVID J. CARIAGA, is an individual and citizen of the County of Honolulu, State of Hawaii, and resides at 92-1120 Panama Street, Apt. 214, Kapolei, Hawaii 96707.
- 3.12. Plaintiff, DAMASE A. CARON, is an individual and citizen of the County of Polk, State of Florida, and resides at 1925 Harden Boulevard, Lot #104, Lakeland, Florida 33803.
- 3.13. Plaintiff, CHARLES RAY COLE, is an individual and citizen of the County of Camden, State of Georgia, and resides at 10 Coastal Walk, Saint Marys, Georgia 31558.
- 3.14. Plaintiff, ROBERT B. COLINI, is an individual and citizen of the County of Broward, State of Florida, and resides at 262 Southwest 53 Avenue, Plantation, Florida 33317.
- 3.15. Plaintiff, SCOTT F. CROMARTY, is an individual and citizen of the County of Hernando, State of Florida, and resides at 7232 Davenport Lane, Springhill, Florida 34606.

- 3.16. Plaintiff, WAYNE R. CUMMINGS, SR., is an individual and citizen of the County of Polk, State of Florida, and resides at 3212 Junction Circle, Lakeland, Florida 33805.
- 3.17. Plaintiff, MACK W. DUKES, JR., is an individual and citizen of the County of Hernando, State of Florida, and resides at 23132 Whitman Road, Brooksville, Florida 34601.
- 3.18. Plaintiff, RODNEY W. EARWOOD, is an individual and citizen of the County of Pasco, State of Florida, and resides at 38033 Bridge Avenue, Zephyrhills, Florida 33541.
- 3.19. Plaintiff, MICHAEL P. EMMONS, is an individual and citizen of the County of Holmes, State of Florida, and resides at 2254 Bonifay Gritney Road, Bonifay, Florida 32425.
- 3.20. Plaintiff, CEPHAS D. ERTZBEREGER, is an individual and citizen of the County of Franklin, State of Georgia, and resides at 13750 Highway 59, Carnesville, Georgia 30521.
- 3.21. Plaintiff, ROBERT F. FEIBUSCH, is an individual and citizen of the County of Broward, State of Florida, and resides at 3950 North 51st Avenue, Hollywood, Florida 33021.
- 3.22. Plaintiff, BARBARA FRANCES GARCIA, is an individual and citizen of the County of Miami-Dade, State of Florida, and resides at 16731 Northwest 78 Place, Miami Lakes, Florida 33016.
- 3.23. Plaintiff, GEORGE EMMA GLASS, is an individual and citizen of the County of Pinellas, State of Florida, and resides at 512 North Washington Avenue, Clearwater, Florida 33755.
- 3.24. Plaintiff, EMMA GOLDEN, is an individual and citizen of the County of Jefferson, State of Georgia, and resides at 402 Pine Valley Circle, #C5, Wrens, Georgia 30833.
- 3.25. Plaintiff, BEATRICE GORDON, is an individual and citizen of the County of Okeechobee, State of Florida, and resides at 1602 Northeast 5th Street, Okeechobee, Florida 34972.
- 3.26. Plaintiff, CONNIE LEE HARMON, is an individual and citizen of the County of Bay, State of Florida, and resides at 2316 Laurie Avenue, Lot 4, Panama City Beach, Florida 32408.

- 3.27. Plaintiff, BARBARA ANN HARVEY, is an individual and citizen of the County of Talbot, State of Georgia, and resides at 5910 Woodland Highway, Woodland, Georgia 31836.
- 3.28. Plaintiff, EMERSON HICKLIN, is an individual and citizen of the County of Clayton, State of Georgia, and resides at 1421 Highgrove Way, College Park, Georgia 30349.
- 3.29. Plaintiff, ROBERT PATRICK HURLEY, is an individual and citizen of the County of Palm Beach, State of Florida, and resides at 5877 Apache Drive, Lake Worth, Florida 33463.
- 3.30. Plaintiff, GENEVA JACKSON-MILLS, is an individual and citizen of the County of New Castle, State of Delaware, and resides at 2805 West 2nd Street, Wilmington, Delaware 19805.
- 3.31. Plaintiff, MICHAEL J. KARATY, JR., is an individual and citizen of the County of Douglas, State of Georgia, and resides at 6550 Phillips Mill Road, Douglasville, Georgia 30135.
- 3.32. Plaintiff, JAMES FREEMAN KING, is an individual and citizen of the County of Dekalb, State of Georgia, and resides at 2806 North Decatur Road, #409, Decatur, Georgia 30033.
- 3.33. Plaintiff, JACK W. KRUSE, is an individual and citizen of the County of Nassau, State of Florida, and resides at 2549 Amelia Road, Fernandina Beach, Florida 32034.
- 3.34. Plaintiff, JOHN A. KUZEMKA, is an individual and citizen of the County of Marion, State of Florida, and resides at 82075 Southeast 175th Columbia Place, The Villages, Florida 32162.
- 3.35. Plaintiff, ROSE A. LOWE, is an individual and citizen of the County of Marion, State of Florida, and resides at 12701 Southeast Sunset Harbor Road, #19, Weirsdale, Florida 32195.
- 3.36. Plaintiff, VERNON EUGENE MEASELS, is an individual and citizen of the County of Hernando, State of Florida, and resides at 33013 Round Table Road, Ridge Manor, Florida

33523.

- 3.37. Plaintiff, GARY DANA MESSMAN, is an individual and citizen of the County of Clayton, State of Georgia, and resides at 6415 Cumberland Drive, Rex, Georgia 30273.
- 3.38. Plaintiff, CHARLES M. MOORE, is an individual and citizen of the County of Polk, State of Florida, and resides at 1234 Reynolds Road, #296, Lakeland, Florida 33801.
- 3.39. Plaintiff, KENNETH BERNARD MOORE, is an individual and citizen of the County of Carroll, State of Georgia, and resides at 15 East Meadowcliff Circle, Carrollton, Georgia 30116.
- 3.40. Plaintiff, GALE J. MORROW, is an individual and citizen of the County of Sarasota, State of Florida, and resides at 5671 Queensbury Boulevard, Sarasota, Florida 34241.
- 3.41. Plaintiff, EARTHA MAE NOBLES, is an individual and citizen of the County of Manatee, State of Florida, and resides at 1103 62nd Avenue East, Bradenton, Florida 34203.
- 3.42. Plaintiff, LARRY RILEY OWENS, is an individual and citizen of the County of Gulf, State of Florida, and resides at 391 West Arm Drive, Wewahitchka, Florida 32465.
- 3.43. Plaintiff, RALPH LEONARD PAYNE, is an individual and citizen of the County of Pinellas, State of Florida, and resides at 8420 Annwood Road, Largo, Florida 33777.
- 3.44. Plaintiff, ALICE N. PIPER, is an individual and citizen of the County of Pinellas, State of Florida, and resides at 1630 58th Avenue South, #3, St. Petersburg, Florida 33712.
- 3.45. Plaintiff, ROGER EDWARD QUILLINGS, is an individual and citizen of the County of Clayton, State of Georgia, and resides at 1100 Misty Meadows Way, Hampton, Georgia 30228.
- 3.46. Plaintiff, ELBERT B. RANDOLPH, is an individual and citizen of the County of Pinellas, State of Florida, and resides at 4906 33rd Street North, St. Petersburg, Florida 33714.

3.47. Plaintiff, GEORGE THOMAS REAGAN, JR., is an individual and citizen of the County of Manatee, State of Florida, and resides at 1416 22nd Avenue West, Bradenton, Florida 34205.

3.48. Plaintiff, JAMES D. REYNOLDS, is an individual and citizen of the County of Union, State of Florida, and resides at 7108 Southwest 139 Lane, Lake Butler, Florida 32054.

3.49. Plaintiff, RUSSELL ROBERT RICHEY, is an individual and citizen of the County of Volusia, State of Florida, and resides at 285 West Park, Lake Helen, Florida 32744.

3.50. Plaintiff, ANGELITA RODRIGUEZ, is an individual and citizen of the County of Osceola, State of Florida, and resides at 3473 Packard Avenue, St. Cloud, Florida 34771.

3.51. Plaintiff, FRED D. SALL, is an individual and citizen of the County of Palm Beach, State of Florida, and resides at 6748 Pisano Drive, Lake Worth, Florida 33467.

3.52. Plaintiff, JAMES R. SEYBOLD, is an individual and citizen of the County of Polk, State of Florida, and resides at 4408 Orangewood Loop East, Lakeland, Florida 33813.

3.53. Plaintiff, ALVESTER SHEFFIELD, JR., is an individual and citizen of the County of Warren, State of Georgia, and resides at 265 Pine Avenue, Warrenton, Georgia 30828.

3.54. Plaintiff, CHARLES WESLEY SMITH, is an individual and citizen of the County of Broward, State of Florida, and resides at 9405 Northwest 70th Place, Tamarac, Florida 33321.

3.55. Plaintiff, MICHAEL LAYVONNE SPARKS, is an individual and citizen of the County of Coffee, State of Georgia, and resides at 305 College Avenue South, Douglas, Georgia 31533.

3.56. Plaintiff, ALLEN E. STARKE, is an individual and citizen of the County of Kent, State of Delaware, and resides at 2907 Skeeter Neck Road, Frederica, Delaware 19946.

- 3.57. Plaintiff, REUBEN W. STEWART, is an individual and citizen of the County of Indian River, State of Florida, and resides at 2150 Pine Creek Boulevard, #103, Vero Beach, Florida 32966.
- 3.58. Plaintiff, MARSHA LYNN STUDLE, is an individual and citizen of the County of Broward, State of Florida, and resides at 613 Northwest 47th Street, Pompano Beach, Florida 33064.
- 3.59. Plaintiff, BARBARA A. TAYLOR, is an individual and citizen of the County of Highlands, State of Florida, and resides at 25 Barra Cuda Drive, Sebring, Florida 33875.
- 3.60. Plaintiff, DENNY L. TAYLOR, is an individual and citizen of the County of Ware, State of Georgia, and resides at 3658 Blue Heron Drive, Waycross, Georgia 31503.
- 3.61. Plaintiff, GERALDINE MARIE TAYLOR-BROWN, is an individual and citizen of the County of New Castle, State of Delaware, and resides at 3014 West 2nd Street, Wilmington, Delaware 19805.
- 3.62. Plaintiff, KENNETH IAN TRAVIS, SR., is an individual and citizen of the County of Hillsborough, State of Florida, and resides at 1307 West Hamilton Avenue, Tampa, Florida 33604.
- 3.63. Plaintiff, LEONARD WENGROW, is an individual and citizen of the County of Dade, State of Florida, and resides at 16558 Northeast 26th Avenue, North Miami Beach, Florida 33160.
- 3.64. Plaintiff, ROBERT A. WILDER, is an individual and citizen of the County of Rockdale, State of Georgia, and resides at 2426 Georgia Highway 20 Southeast, Conyers, Georgia 30013.
- 3.65. Plaintiff, RANDALL SCOTT WILLIAMS, is an individual and citizen of the County of Dade, State of Florida, and resides at 395 Northwest 177th Street, Miami Gardens, Florida 33169.

3.66. Plaintiff, DAVE WILSON, is an individual and citizen of the County of Cobb, State of Georgia, and resides at 825 Powder Springs Street, Apt. 207, Marietta, Georgia 30064.

4. Defendant Medtronic, Inc., is a Minnesota corporation, with its principal place of business at 710 Medtronic Parkway, Minneapolis, Minnesota 55432. Medtronic designs, manufactures and markets medical devices worldwide. Medtronic's Cardiac Rhythm Disease Management Division ("CRM Division") which is primarily responsible for Medtronic's ICDs, and leads, including the Sprint Fidelis Leads are principally conducted out of its facilities at Cardiac Rhythm Disease Management. at 7000 Central Avenue, Minneapolis, Minnesota 55432.

5. Defendant Medtronic International Technology, Inc. (formerly known as Medtronic Puerto Rico, Inc.) is a Minnesota corporation, with its principal place of business at Road 149, km 56.3, Box 6001 Villalba, Puerto Rico.

6. Defendant Medtronic Puerto Rico Operations Co. is a corporation existing by virtue of the laws of the Cayman Islands, with its principal place of business at Road 149, km 56.3, Box 6001 Villalba, Puerto Rico.

7. Medtronic International Technology, Inc., and Medtronic Puerto Rico Operations Co. are wholly owned subsidiaries of Medtronic, Inc., which formulate, develop, manufacture and sterilize the devices at issue in this lawsuit.

8. At all relevant times, each of the Defendants and their directors and officers acted within the scope of their authority and on behalf of each other Defendant. During the relevant times, Defendants possessed a unity of interest between themselves and Medtronic exercised control over its subsidiaries and affiliates. As such, each Defendant is individually, as well as jointly and severally, liable to Plaintiffs for Plaintiffs' damages.

III. INTRODUCTION

9. Medtronic designs, researches, develops, manufactures, tests, markets, advertises, promotes, distributes, and sells products that treat cardiac arrhythmia, heart failure, and coronary and peripheral vascular disease. An arrhythmia is an irregular cardiac rhythm, which can cause significantly decreased cardiac output and ultimately, death. Medtronic holds itself out as “the global leader in medical technology, alleviating pain, restoring health and extending life for millions of people around the world.” *See* 2005 Annual Statement, Medtronic, Inc.
10. A number of devices designed to detect and treat abnormally fast and irregular heart rhythms and to provide pacing for improper heart rhythms are available from Medtronic and other manufacturers, including implantable cardiac defibrillators (“ICDs”). ICDs contain pacemakers as well as defibrillators; while a pacemaker is used primarily to correct slow heart rates, an ICD detects and corrects both fast and slow heart rates. The pacemaker portion corrects the slow rates and the anti-tachycardia portion can “over-drive pace” rapid rates. The defibrillator portion can shock ventricular tachycardia and ventricular fibrillation to stop the heart and allow an appropriate rhythm to take over.
11. ICDs are designed to be implanted primarily under the skin of the chest wall. The device’s power source, or pulse generator, is implanted in a pouch formed in the chest wall generally over the left pectoralis major muscle.
12. Typically, wires called Leads are inserted through a major vein and attached directly to the muscle on the inside of the heart. Electrodes that sense the heart’s rhythm are built into the lead wires and positioned in the heart, where they monitor the heartbeat and can administer an electric shock to abort a dangerous “over-drive pace,” a very rapid rhythm, or pace the heart at a normal rhythm if an irregularity is detected.

13. Such devices are used in patients, like the Plaintiffs, who have arrhythmia or irregular heartbeats that are considered life-threatening. These arrhythmia or irregular heart beats can result in the loss of consciousness or death, unless the patient receives therapy from an appropriate device to put the heart back into an appropriate cardiac rhythm.
14. If an implanted ICD and Lead operate properly, the system can save a patient's life. If either fails to operate, the patient may die within minutes.

IV. THE SPRINT FIDELIS LEADS

15. This Action seeks recovery for patients who have been implanted with Sprint Fidelis Leads marketed by Medtronic under the following model numbers: (a) the 6949 LFJ extendable/retractable screw fixation (S) model; (b) the 6948 LFH tuned fixation (T) model; (c) the 6931 LFT S fixation; and (d) the 6930 LFK T fixation.
16. At all times relevant, these Sprint Fidelis Leads were researched, developed, manufactured, marketed, promoted, advertised, sold, and distributed by Medtronic to be used in connection with ICDs.
17. The majority of ICDs now use two or three Leads. As a result, smaller high-voltage Leads are attractive to electrophysiologists because they are believed to be easier to insert, and are less likely to obstruct blood flow or distort the tricuspid valve. The Medtronic Sprint Fidelis Leads are smaller high voltage Leads.
18. In November 2001, Medtronic began marketing the Sprint Quattro Secure, Model 6947 ("Quattro Leads"). The lead has a diameter of 8.6 French.¹
19. Medtronic continued to develop ever smaller diameter defibrillation leads and in late 2003

¹ French is a measure of diameter. One French is equal to 0.33 mm, or approximately 0.012 inches.

filed premarket approval supplements with the U. S. Food and Drug Administration for the Sprint Fidelis line of leads resting upon a premarket approval of the Medtronic Transvene Lead System originally granted on December 9, 1993. See <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/PMA.cfm?ID=28>; <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/PMA.cfm?ID=10279>; <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/PMA.cfm?ID=10280>.

20. On June 8, 2004, the family of four Sprint Fidelis Leads received premarket approval. The approvals were for the addition of a polyurethane overlay which apparently allowed for a smaller diameter lead, because the Sprint Fidelis Leads have a nominal diameter of 6.6 French; about 0.66 mm less than the comparable Sprint Quattro Secure lead.
21. A later premarket approval was granted on December 1, 2005, for a supplement to approve a change in the aeration time following sterilization of the leads. See <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/PMA.cfm?ID=10282>.
22. After premarket approval, Medtronic introduced to the marketplace the Sprint Fidelis Model 6930 Lead in June 2004, and the Models 6931, 6948, and 6949 Leads in September 2004 to replace the Sprint Quattro Secure as the high voltage lead of choice and to attempt to gain a larger market share.
23. Medtronic claimed that “the small size of the Sprint Fidelis (Fidelis is a Latin word that means ‘faithful’) helps improve passage into a patient’s venous system for an easier implant, and minimizes venous obstruction.” Medtronic also referred to the Leads as “state-of-the-art.”
24. The Sprint Fidelis family of Leads are bipolar high voltage leads with silicone insulation and a polyurethane outer coating. The Models 6949 and 6948 have two high voltage coils; the

6930 and 6931 models have a single right ventricular high voltage coil. As of January 2007, approximately 144,311 Model 6949 Sprint Fidelis Leads, 7,510 Model 6948 Leads, 5,387 Model 6931 Leads, and 236 Model 6930 Leads had been implanted.

25. Clinical data for the 6947 Sprint Quattro Secure Lead was used to support the safety and efficiency of the 6949 Sprint Fidelis Lead, accordingly clinical data were not collected for premarket approval of the 6949 Sprint Fidelis Lead. *See* 6949 Technical Manual, copyright 2004, Medtronic, Inc.

V. DEFECTS IN THE SPRINT FIDELIS LEADS

26. Once the Sprint Fidelis Leads were introduced to the market, it became quickly evident that a significant portion of the Leads had potentially fatal defects.

27. Such defects were discussed in an article written by doctors at The Minneapolis Heart Institute, one of the premiere heart institutes in the world, based on a study of the incidence of lead failures in the Sprint Fidelis Models compared to the Sprint Quattro Models. According to the report, which was prepared by Dr. Robert G. Hauser, *et al.*, and published in the Heart Rhythm Society Journal in the Spring of 2007, “Early Failure of Small-Diameter High-Voltage Inflammable Cardioverter-Defibrillator Lead”, Heart Rhythm Society 2007.03.041 (2007) (“Early Failure”), the Minneapolis Heart Institute’s experience reflected that, between September 2004 and February 2007, 583 patients were implanted with Sprint Fidelis Model 6949 Leads, and nine patients received other Sprint Fidelis models. During that time, six patients experienced Sprint Fidelis Model 6949 Lead failures. The failed Sprint Fidelis Model 6949 Leads had been implanted by various electrophysiologists, cardiologists and thoracic surgeons. The average time to failure was fourteen months (based on a range of four to twenty-three months). *Early Failure*, p. 893.

28. The study compared the actuarial survival of the 583 Sprint Fidelis Model 6949 Leads implanted at the Minneapolis Heart Institute to the survival of 285 Sprint Quattro Model 6947 Leads implanted at the Institute between November 2001 and March 2007. The difference in survival between the Sprint Fidelis Model 6949 lead and the Sprint Quattro Secure Model 6947 lead was extremely significant. The failure rate for the Sprint Fidelis Model 6949 lead was 1-2% during the first two years of implant and was ten times greater than the failure rate for the Sprint Quattro Secure Model 6947 lead. *Early Failure*, p. 893-894.
29. The significant number of lead failures involved lead fractures of the PACE-sense conductor or coil in the Model 6949 Sprint Fidelis Lead. The fracture rate for the Sprint Fidelis Leads was three times higher than the fracture rate of the Quattro Model 6947. *Early Failure*, p. 894-895.
30. Another study, conducted at Cornell University Medical Center by Sunil Mirchandani, *et al.*, found “[a] 17% incidence of abnormal right ventricular sensing during follow-up of patients implanted with the Medtronic Sprint Fidelis ICD Lead,” necessitating “an early revision of the system in 4% of patients.” See Abstract of *Defibrillator Leads: Is Smaller Necessarily Better?*, 2006, available at <http://vivo.library.cornell.edu/entity?home=&id=30168>.
31. Medtronic has not disclosed the precise mechanism of the Sprint Fidelis Lead fracture failures. In a letter to healthcare providers dated October 15, 2007, Medtronic disclosed two primary locations where chronic conductor fractures have occurred in Sprint Fidelis leads:
 - a. the distal portion of the lead, affecting the anode (ring electrode); and
 - b. near the anchoring sleeve tie-down, predominantly affecting the cathode (helix tip electrode), and occasionally the high voltage conductor.

See Urgent Medical Device Information, dated October 15, 2007, Medtronic, Inc.

Medtronic further noted that high voltage conductor fractures could result in the inability to deliver defibrillation therapy. *Id.* Anode or cathode conductor fractures (at either location) may present clinically as increased impedance, oversensing, increased interval counts, multiple inappropriate shocks, and/or loss of pacing output. *Id.* The potential for defibrillation lead fracture to result in or contribute to inappropriate therapies or death has been previously reported. *Id.* Based on current information, Medtronic had identified five patient deaths in which a Sprint Fidelis lead fracture may have been a possible or likely contributing factor. *Id.* Medtronic further confirmed 665 chronic fractures in returned leads. *Id.* Approximately 90% of the fractures occurred in the anode or cathode conductors, while 10% have occurred in the high voltage conductors. *Id.*

32. It appears that the majority of defects, among other possible defects known to Medtronic but not revealed to Plaintiffs, reported by Medtronic in the Sprint Fidelis Leads may be attributable to the small diameter of the coil and conductors and the fact that, in light of this small diameter, it is subject to stress damage both during and after implant. Fracture eventually occurs when the conductor is critically over-stressed. The number of fractures that have been observed in these Leads indicates that there is a clear defect in the Leads themselves, and that defect was demonstrated or will most certainly occur in the 6930, 6031, 6948, or 6949 Sprint Fidelis Lead that was implanted in Plaintiffs.
33. A review of the FDA's Manufacturer and User Facility Device Experience Database, ("MAUDE database"), which contains reports of adverse events associated with the use of medical devices, discloses that, as of July 2007, over 1000 Medical Device Reports ("MDR"s) regarding Sprint Fidelis lead had been filed since September 2004. The most

frequent complaints were fracture and inappropriate shocks, and the most common observations were high impedance, over-sensing and noise, and failure to capture or high threshold.

34. Medtronic analyzed approximately 125 of those Leads that were returned to Medtronic before July 2006. According to the relevant MDR reports, Medtronic concluded that 77 out of 125 Leads (or 62%) were defective. The predominant manifestation of the defect was conductor fracture, involving the PACE-sense conductor and coil or the high voltage (defibrillation) conductor. PACE-sense conductor or coil fracture was manifested by inappropriate shocks or oversensing/noise and high impedance, while high voltage conductor fracture was primarily linked to high impedance.
35. Medtronic filed more than 350 additional MDRs regarding the Sprint Fidelis Leads between August 2006 and February 2007. Medtronic did not include similar analyses as above of those Leads in the MDRs filed by it during this later period.
36. On March 21, 2007, Medtronic issued its first physician advisory, in the nature of a “Dear Doctor Letter,” that advised physicians of “the higher than expected conductor fracture rates in Sprint Fidelis Leads.” Medtronic claims in that letter to be investigating reports of lead failures; however, still represented that the Sprint Fidelis Leads were performing consistent with, and “in line with other Medtronic Leads, and consistent with lead performance publicly reported by other manufacturers.” The letter also stated, “...variables within the implant procedure may contribute significantly to these fractures... For conductor fractures that occur around the suture sleeve, our preliminary investigation suggests that under certain implant techniques, the lead appears to be exposed to severe bending or kinking in the pectoral area.” At no time prior to this letter did Medtronic warn physicians that its Leads

must be specially handled during the implantation procedure or that they could “severely bend” or “kink” if they are implanted using certain accepted implant techniques.

37. On October 15, 2007, Medtronic announced a recall of all un-implanted Sprint Fidelis Leads, citing several deaths related to the Leads. Medtronic recommended that implanted Sprint Fidelis Leads be monitored.
38. Medtronic’s representation of the consistency of the performance of the Sprint Fidelis Leads is untrue in light of the reported experience with the Leads and the various issues included in the MAUDE database reports.

VI. ALLEGATIONS

39. At all times relevant, Medtronic misrepresented the safety of the Sprint Fidelis Leads and negligently manufactured, marketed, advertised, promoted, sold, and distributed the Leads as safe devices to be used together with ICDs for prophylactic treatment of patients with prior myocardial infarction and decreased ejection fraction, ventricular arrhythmia, and patients who are at high risk for developing such arrhythmia. Some patients are dependent on such devices to maintain an appropriate heart rhythm, and therefore, adequate cardiac output. For these patients, failure of the Leads connected to the ICD can cause sudden faintness, or loss of consciousness, and can result in death.
40. At all times relevant, Medtronic failed to warn that the Sprint Fidelis leads were prone to breakage or that particular processes should be implemented in order to avoid breaking the Sprint Fidelis Leads.
41. As a result of their defective design and manufacture, Medtronic’s Sprint Fidelis Leads suffer fracture, leading to malfunction in the transmission of the electric signal from the ICD to the patient’s heart.

42. At all times relevant, the Sprint Fidelis (collectively the "Leads") were researched, developed, manufactured, marketed, promoted, advertised and sold by Medtronic.
43. At all times relevant, Medtronic misrepresented the safety of the Sprint Fidelis Leads, and negligently manufactured, marketed, advertised, promoted, sold and distributed the Leads as safe and effective devices to be used for implantation with ICDs for prophylactic treatment of patients with prior myocardial infarction and a limited ejection fraction, patients who have had spontaneous and/or inducible life-threatening ventricular arrhythmia, and patients who are at high risk for developing such arrhythmia.
44. At all times relevant to this action, Medtronic knew, and had reason to know, that the Sprint Fidelis Leads were not safe for the patients for whom they were prescribed and implanted, because the Leads fractured and otherwise malfunctioned, and therefore failed to operate in a safe and continuous manner, causing serious medical problems and, in some patients, catastrophic injuries and deaths.
45. At all times relevant to this action, Medtronic knew, and had reason to know, that its representations that the Sprint Fidelis Leads were easier to implant based on "proven" technology were materially false and misleading.
46. Approximately 129,000 of the affected devices remain in service in the United States and in other countries.
47. As a result of this defective design and manufacture, the Sprint Fidelis Leads can cause serious physical trauma and/or death. Medtronic knew and had reason to know of this tendency and the resulting risk of injuries and deaths, but concealed this information and did not warn Plaintiffs' physicians, preventing Plaintiffs and their physicians, and the medical community from making informed choices about the selection of Leads for implantation.

Medtronic designed, manufactured, marketed, promoted, sold, and distributed four models of defective Leads, including the Sprint Fidelis 6949 LFJ extendable/retractable screw fixation (S) model; the 6948 LFH tuned fixation (T) model; the 6931 LFT S fixation; and the 6930 LFK fixation (T) model. All of the aforementioned models contain the same defects.

48. The Sprint Fidelis Leads are uniformly defective in that they are prone to fracture of the pace-sense conductor and coil and the HV conductor, causing them to fail to function in a manner which may not be immediately detectable by the patient. The malfunctioning can lead to terrifying inappropriate defibrillation shocks, failure to deliver appropriate (life-giving) defibrillation therapy and death.
49. There is no test that predicts whether or when the Sprint Fidelis Leads will fail.
50. To this day, Medtronic has refused to suggest replacement of the defective Sprint Fidelis Leads in its patients, even though in patients whom these defects have been discovered, emergency replacement of the Leads is required.
51. Medtronic's failure to document or follow-up on the known defects in its Sprint Fidelis Leads, and concealment of known defects from the FDA, patients and the medical community constitutes fraudulent concealment that equitably tolls applicable statutes of limitation.
52. Medtronic is estopped from relying on the Statute of Limitations defense because Medtronic actively concealed the lead defects, suppressing reports, failing to follow through on FDA notification requirements, and failing to disclose known defects to physicians or patients. Instead of revealing the defects, Medtronic continued to represent its products as safe for their intended use.

53. Medtronic's conduct, as described in the preceding paragraphs, amounts to conduct intentionally committed, which Medtronic must have realized was dangerous, wanton and reckless, without regard to the consequences, rights and safety of patients.
54. Medtronic's failure to provide adequate and accurate information has resulted in thousands of patients' relying upon the proper functioning of these Sprint Fidelis Leads, and they, along with their physicians, have been vigorously attempting to assess the risks that they now face.
55. Patients and physicians remain uninformed and confused about whether the devices should be explanted, or even whether all of the defects have been disclosed.
56. Due to incomplete, inconsistent, and/or confusing information published by Medtronic it remains unclear as to how many patients are affected by these defective Leads.
57. At all times herein mentioned, each of the Defendants was the agent, servant, partner, aider and abettor, co-conspirator and/or joint venturer of the other Defendants herein and was at all times operating and acting within the purpose and scope of said agency, service, employment, partnership, conspiracy and/or joint venture and rendered substantial assistance and encouragement to the other Defendants, knowing that their collective conduct constituted a breach of duty owed to Plaintiffs.
58. There exists and, at all times herein mentioned, existed a unity of interest in ownership between certain Defendants and other certain Defendants such that any individuality and separateness between the certain Defendants has ceased and these Defendants are the alter ego of the other certain Defendants and exerted control over those Defendants. Adherence to the fiction of the separate existence of these certain Defendants as entities distinct from other certain Defendants will permit an abuse of the corporate privilege and would sanction

a fraud and/or would promote injustice.

59. At all times herein mentioned, Defendants, were engaged in the business of, or were successors in interest to, entities engaged in the business of researching, designing, formulating, compounding, testing, manufacturing, producing, processing, assembling, inspecting, distributing, marketing, labeling, promoting, packaging, prescribing and/or advertising for sale, and selling products for use by Plaintiffs. As such, each Defendant is individually, as well as jointly and severally, liable to Plaintiffs for damages.
60. At all times herein mentioned, the officers and/or directors of the Defendants named herein, participated in, authorized and/or directed the production and promotion of the aforementioned products when they knew, or with the exercise of reasonable care and diligence should have known, of the hazards and dangerous propensities of said products, and thereby actively participated in the tortious conduct that resulted in the injuries suffered by Plaintiffs.
61. At all times relevant, Medtronic received additional evidence of numerous defects in the Sprint Fidelis Leads after premarket approval of the supplements which were submitted for these leads. The defects reported by Medtronic to Plaintiffs were and are of a nature different than the subject matter of the premarket approval supplements; which were the addition of a polyurethane overlay and a change in sterilization procedures. Medtronic had a statutory and regulatory duty to periodically update its premarket supplements with new safety or effectiveness information that reasonably affected the safety or effectiveness of the previously approved Leads, which it failed to do.
62. At all times relevant, Medtronic failed to comply with the applicable provisions of 21 C. F. R. Part 814, PreMarket Approval of Medical Devices, and 21 C. F. R. Part 820, Quality

System Regulation, which rendered the Sprint Fidelis Leads adulterated under 21 U. S. C. 351(h), thereby subjecting the Leads and Medtronic subject to regulatory action. 21 C. F. R. 820.1(c). Federal law does not prevent Plaintiffs from seeking damages for her claims based on violations of FDA regulations or where evidence of the Sprint Fidelis Leads' defects came to light only after their premarket approval.

63. At all times relevant, Medtronic violated the procedures and actions that apply to PMA supplements pursuant to 21 C. F. R. 814.39 by failing to amend or supplement its prior premarket approval supplements for the Sprint Fidelis Leads with new safety and effectiveness information required by 21 C. F. R. 814.20. Under 21 C. F. R. 814.20 and 814.39, Medtronic violated its regulatory duty to periodically update its premarket approval supplements with new safety and effectiveness information learned about the Sprint Fidelis Leads from ongoing or completed studies that reasonably affected the evaluations of their safety or effectiveness or that reasonably affected the statements of contraindications, warnings, precautions, and adverse reactions in their labeling.
64. At all times relevant, Medtronic failed to maintain the Design Controls mandated by 21 C. F. R. 820.30. Specifically;
 - a. Medtronic violated the regulation pertaining to Design and Development Planning by failing to establish and maintain plans that described or referenced the design and development activities regarding the Sprint Fidelis leads;
 - b. Medtronic violated the regulation pertaining to Design Input by failing to establish and maintain procedures to ensure that the design requirements relating to the Sprint Fidelis Leads were appropriate and addressed the intended use of the devices, including the needs of the user and patient and were properly documented;

- c. Medtronic violated the regulation regarding Design Output by failing to establish and maintain procedures for defining and documenting design output in terms that allowed an adequate evaluation of conformance to design input requirements and to document, review, and approve the design output before release;
- d. Medtronic violated the regulation regarding Design Review by failing to establish and maintain procedures to ensure that formal documented reviews of the Sprint Fidelis Leads' design results were planned and conducted at appropriate stages of the Leads' design development;
- e. Medtronic violated the regulation concerning Design Verification by failing to establish and maintain procedures for verifying the design of the Sprint Fidelis Lead and confirming that the design output meets the design input requirements;
- f. Medtronic violated the regulation pertaining to Design Validation by failing to establish and maintain procedures for validating the design of the Sprint Fidelis Leads under defined operating conditions on initial production units, lots, or batches, or their equivalents, ensuring that the Leads conformed to defined user needs and intended uses, and failing to perform testing of production units under actual or simulated use conditions;
- g. Medtronic violated the regulation concerning Design Transfer by failing to establish and maintain procedures to ensure that the design of the Sprint Fidelis Leads correctly translated into production specifications; and
- h. Medtronic violated the regulation pertaining to Design Changes by failing to establish and maintain procedures for the identification, documentation, validation or where appropriate verification, review, and approval of design changes before

their implementation.

65. At all times relevant, Medtronic failed to maintain the Production and Process Controls mandated by 21 C. F. R. 820.70. Specifically;
 - a. Medtronic violated the regulation by failing to conduct, control, and monitor its production processes to ensure that the Sprint Fidelis Leads conformed to their specifications; and
 - b. Medtronic violated the regulation regarding Production and Process Changes by failing to establish and maintain procedures for changes to specifications, methods, processes, or procedures for manufacturing the Sprint Fidelis Leads, by failing to verify or validate the changes according to 21 C. F. R. 820.75 before implementation, and by failing to obtain approval of the changes in accordance with 21 C. F. R. 820.40.
66. At all times relevant, Medtronic failed to perform the Process Validation mandated by 21 C. F. R. 820.75. Specifically;
 - a. Medtronic violated the regulation when it failed to validate the Sprint Fidelis Lead manufacturing process with a high degree of assurance and under approved and established procedures, and failing to document the validation with the appropriate dates and signatures of the individual(s) approving it, and including the major equipment validated;
 - b. Medtronic violated the regulation when it failed to establish and maintain procedures for monitoring and control of process parameters for the validated processes to manufacture the Sprint Fidelis Leads to ensure that the specified requirements continued to be met, by failing to ensure that validated processes were performed by

qualified individual(s), and by failing to document, monitor and control the methods and data, the date performed, and, where appropriate, the individual(s) performing the process or the major equipment used; and

c. Medtronic violated the regulation when it failed to review, evaluate, and document the process and perform revalidation when changes or process deviations occurred.

67. At all times relevant, Medtronic failed to take Corrective and Preventive Action mandated by 21 C. F. R. 820.100. Specifically;

a. Medtronic violated the regulation when it failed to establish and maintain procedures and document corrective and preventive action, including but not limited to analyzing processes, work operations, concessions, quality audit reports, quality records, service records, complaints, returned product, and other sources of quality data to identify existing and potential causes of nonconforming product, or other quality problems; investigating the cause of nonconformities relating to product, processes, and the quality system; identifying the action(s) needed to correct and prevent recurrence of nonconforming product and other quality problems; verifying or validating the corrective and preventive action to ensure that such action is effective and does not adversely affect the finished device; implementing and recording changes in methods and procedures needed to correct and prevent identified quality problems; ensuring that information related to quality problems or nonconforming product is disseminated to those directly responsible for assuring the quality of such product or the prevention of such problems; and submitting relevant information on identified quality problems, as well as corrective and preventive actions, for management review.

68. At all times relevant, Medtronic failed to provide adequate Installation instructions for the Sprint Fidelis Leads, as required by 21 C. F. R. 820.170. Specifically;

- a. Medtronic violated the regulation by failing to establish and maintain adequate installation and inspection instructions, and where appropriate test procedures. Medtronic's instructions and procedures failed to include directions for ensuring proper installation so that the device will perform as intended after installation.

VII. PLAINTIFFS

- 69.1. On July 6, 2006, Plaintiff, MELVIN ABROTSKY, had implanted a Medtronic Sprint Fidelis Lead, Model No. 693165ID, Serial No. LFL004966V.
- 69.2. On May 7, 2007, Plaintiff, STEVEN NELS ASLIN, had implanted a Medtronic Sprint Fidelis Lead, Model No. 6949, Serial No. LFJ230393V.
- 69.3. On September 25, 2006, Plaintiff, WILLIAM PAUL BARNETT, had implanted a Medtronic Sprint Fidelis Lead, Model No. 694965, Serial No. LFJ143834V.
- 69.4. On February 9, 2006, Plaintiff, STANLEY WAYNE BAZEMORE, had implanted a Medtronic Sprint Fidelis Lead, Model No. 694965ID, Serial No. LFJ106691V.
- 69.5. On September 14, 2005, Plaintiff, JOSEPH F. BEVILACQUA, had implanted a Medtronic Sprint Fidelis Lead, Model No. 694965ID, Serial No. LFJ086194V.
- 69.6. On January 18, 2006, Plaintiff, SANDRA CHRISTINA BLACK, had implanted a Medtronic Sprint Fidelis Lead, Model No. 694965ID, Serial No. LFJ115030V.
- 69.7. On April 1, 2005, Plaintiff, CONNIE G. BOWLING, had implanted a Medtronic Sprint Fidelis Lead, Model No. 694965ID, Serial No. LFJ045458V.
- 69.8. On August 3, 2007, Plaintiff, JAMES EDWARD BROADWAY, had implanted a Medtronic Sprint Fidelis Lead, Model No. 694958ID, Serial No. LFJ195051V.

69.9. On June 8, 2005, Plaintiff, MILTON BULLARD, JR., had implanted a Medtronic Sprint Fidelis Lead, Model No. 694965ID, Serial No. LFJ052047V.

69.10. On April 27, 2007, Plaintiff, JOHN P. CACHIOLI, had implanted a Medtronic Sprint Fidelis Lead, Model No. 694958ID, Serial No. LFJ221362V.

69.11. On March 15, 2006, Plaintiff, DAVID J. CARIAGA, had implanted a Medtronic Sprint Fidelis Lead, Model No. 694965ID, Serial No. LFJ125964V.

69.12. On August 9, 2006, Plaintiff, DAMASE A. CARON, had implanted a Medtronic Sprint Fidelis Lead, Model No. 694965ID, Serial No. LFJ151424V.

69.13. On May 31, 2005, Plaintiff, CHARLES RAY COLE, had implanted a Medtronic Sprint Fidelis Lead, Model No. 694965ID, Serial No. LFJ051030V.

69.14. On December 20, 2005, Plaintiff, ROBERT B. COLINI, had implanted a Medtronic Sprint Fidelis Lead, Model No. 694965ID, Serial No. LFJ107931V.

69.15. On October 5, 2006, Plaintiff, SCOTT F. CROMARTY, had implanted a Medtronic Sprint Fidelis Lead, Model No. 694965, Serial No. LFJ142427V.

69.16. On November 8, 2004, Plaintiff, WAYNE R. CUMMINGS, SR., had implanted a Medtronic Sprint Fidelis Lead, Model No. 694965ID, Serial No. LFJ018167V.

69.17. On July 25, 2006, Plaintiff, MACK W. DUKES, JR., had implanted a Medtronic Sprint Fidelis Lead, Model No. 694965ID, Serial No. LFJ164077V.

69.18. On February 15, 2006, Plaintiff, RODNEY W. EARWOOD, had implanted a Medtronic Sprint Fidelis Lead, Model No. 694965, Serial No. LFJ138953V.

69.19. On September 1, 2005, Plaintiff, MICHAEL P. EMMONS, had implanted a Medtronic Sprint Fidelis Lead, Model No. 694865ID, Serial No. LFH003073R.

69.20. On November 2, 2004, Plaintiff, CEPHAS D. ERTZBERGER, had implanted a Medtronic

Sprint Fidelis Lead, Model No. 694965ID, Serial No. LFJ006255V.

69.21. On February 3, 2005, Plaintiff, ROBERT F. FEIBUSCH, had implanted a Medtronic Sprint Fidelis Lead, Model No. 694965ID, Serial No. LFJ029936V.

69.22. On February 16, 2007, Plaintiff, BARBARA FRANCES GARCIA, had implanted a Medtronic Sprint Fidelis Lead, Model No. 693058ID, Serial No. LFK003779V.

69.23. On May 9, 2006, Plaintiff, GEORGE EMMA GLASS, had implanted a Medtronic Sprint Fidelis Lead, Model No. 694965ID, Serial No. LFJ135717V.

69.24. On May 12, 2005, Plaintiff, EMMA GOLDEN, had implanted a Medtronic Sprint Fidelis Lead, Model No. 694965ID, Serial No. LFJ050646V.

69.25. On October 14, 2005, Plaintiff, BEATRICE GORDON, had implanted a Medtronic Sprint Fidelis Lead, Model No. 6949, Serial No. LFJ080296V.

69.26. On April 28, 2006, Plaintiff, CONNIE LEE HARMON, had implanted a Medtronic Sprint Fidelis Lead, Model No. 694865ID, Serial No. LFH015993V.

69.27. On June 7, 2006, Plaintiff, BARBARA ANN HARVEY, had implanted a Medtronic Sprint Fidelis Lead, Model No. 694965ID, Serial No. LFJ184800V.

69.28. On February 5, 2007, Plaintiff, EMERSON HICKLIN, had implanted a Medtronic Sprint Fidelis Lead, Model No. 694965ID, Serial No. LFJ210356V.

69.29. On November 24, 2004, Plaintiff, ROBERT PATRICK HURLEY, had implanted a Medtronic Sprint Fidelis Lead, Model No. 694958ID, Serial No. LFJ007102V.

69.30. On May 30, 2007, Plaintiff, GENEVA JACKSON-MILLS, had implanted a Medtronic Sprint Fidelis Lead, Model No. 694965ID, Serial No. LFJ244430V.

69.31. On October 24, 2005, Plaintiff, MICHAEL J. KARATY, JR., had implanted a Medtronic Sprint Fidelis Lead, Model No. 694965ID, Serial No. LFJ088501V.

69.32. On November 27, 2006, Plaintiff, JAMES FREEMAN KING, had implanted a Medtronic Sprint Fidelis Lead, Model No. 694958, Serial No. LFJ189315V.

69.33. On December 15, 2006, Plaintiff, JACK W. KRUSE, had implanted a Medtronic Sprint Fidelis Lead, Model No. 6949-65CM, Serial No. LFJ200927V.

69.34. On May 19, 2005, Plaintiff, JOHN A. KUZEMKA, had implanted a Medtronic Sprint Fidelis Lead, Model No. 694958ID, Serial No. LFJ012390V.

69.35. On November 8, 2006, Plaintiff, ROSE A. LOWE, had implanted a Medtronic Sprint Fidelis Lead, Model No. 694958ID, Serial No. LFJ194870V.

69.36. On May 30, 2007, Plaintiff, VERNON EUGENE MEASELS, had implanted a Medtronic Sprint Fidelis Lead, Model No. 694965ID, Serial No. LFJ235224V.

69.37. On September 19, 2006, Plaintiff, GARY DANA MESSMAN, had implanted a Medtronic Sprint Fidelis Lead, Model No. 694965ID, Serial No. LFJ143074V.

69.38. On March 24, 2006, Plaintiff, CHARLES M. MOORE, had implanted a Medtronic Sprint Fidelis Lead, Model No. 694965ID, Serial No. LFJ130268V.

69.39. On April 26, 2006, Plaintiff, KENNETH BERNARD MOORE, had implanted a Medtronic Sprint Fidelis Lead, Model No. 694965ID, Serial No. LFJ138084V.

69.40. On March 23, 2005, Plaintiff, GALE J. MORROW, had implanted a Medtronic Sprint Fidelis Lead, Model No. 694958ID, Serial No. LFJ033804V.

69.41. On August 26, 2005, Plaintiff, EARTHA MAE NOBLES, had implanted a Medtronic Sprint Fidelis Lead, Model No. 694965ID, Serial No. LFJ083606V.

69.42. On December 22, 2006, Plaintiff, LARRY RILEY OWENS, had implanted a Medtronic Sprint Fidelis Lead, Model No. 694865ID, Serial No. LFH002449R.

69.43. On February 21, 2007, Plaintiff, RALPH LEONARD PAYNE, had implanted a Medtronic

Sprint Fidelis Lead, Model No. 694965ID, Serial No. LFJ208758V.

69.44. On October 4, 2006, Plaintiff, ALICE N. PIPER, had implanted a Medtronic Sprint Fidelis Lead, Model No. 694958ID, Serial No. LFJ173357V.

69.45. On December 20, 2004, Plaintiff, ROGER EDWARD QUILLINGS, had implanted a Medtronic Sprint Fidelis Lead, Model No. 694958ID, Serial No. LFJ025204V.

69.46. On May 25, 2007, Plaintiff, ELBERT B. RANDOLPH, had implanted a Medtronic Sprint Fidelis Lead, Model No. 694958ID, Serial No. LFJ212203V.

69.47. On January 17, 2007, Plaintiff, GEORGE THOMAS REAGAN, JR., had implanted a Medtronic Sprint Fidelis Lead, Model No. 694965ID, Serial No. LFJ203224V.

69.48. On June 6, 2006, Plaintiff, JAMES D. REYNOLDS, had implanted a Medtronic Sprint Fidelis Lead, Model No. 694958ID, Serial No. LFJ137389V.

69.49. On August 9, 2007, Plaintiff, RUSSELL ROBERT RICHEY, had implanted a Medtronic Sprint Fidelis Lead, Model No. 694965ID, Serial No. LFJ251967V.

69.50. On April 27, 2007, Plaintiff, ANGELITA RODRIGUEZ, had implanted a Medtronic Sprint Fidelis Lead, Model No. 694958ID, Serial No. LFJ236796V.

69.51. On September 29, 2006, Plaintiff, FRED D. SALL, had implanted a Medtronic Sprint Fidelis Lead, Model No. 694965ID, Serial No. LFJ143592V.

69.52. On July 26, 2005, Plaintiff, JAMES R. SEYBOLD, had implanted a Medtronic Sprint Fidelis Lead, Model No. 694965ID, Serial No. LFJ073110V.

69.53. On August 15, 2006, Plaintiff, ALVESTER SHEFFIELD, JR., had implanted a Medtronic Sprint Fidelis Lead, Model No. 694965ID, Serial No. LFJ151429V.

69.54. On April 19, 2005, Plaintiff, CHARLES WESLEY SMITH, had implanted a Medtronic Sprint Fidelis Lead, Model No. 694965ID, Serial No. LFJ049869V.

69.55. On April 5, 2006, Plaintiff, MICHAEL LAYVONNE SPARKS, had implanted a Medtronic Sprint Fidelis Lead, Model No. 694965ID, Serial No. LFJ132275V.

69.56. On October 5, 2007, Plaintiff, ALLEN E. STARKE, had implanted a Medtronic Sprint Fidelis Lead, Model No. 694965, Serial No. LFJ260929V.

69.57. On February 19, 2006, Plaintiff, REUBEN W. STEWART, had implanted a Medtronic Sprint Fidelis Lead, Model No. 694965ID, Serial No. LFJ120005V.

69.58. On August 20, 2007, Plaintiff, MARSHA LYNN STUDLE, had implanted a Medtronic Sprint Fidelis Lead, Model No. 6949-58, Serial No. LFJ223080V.

69.59. On July 18, 2007, Plaintiff, BARBARA A. TAYLOR, had implanted a Medtronic Sprint Fidelis Lead, Model No. 694965ID, Serial No. LFJ252080V.

69.60. On January 17, 2006, Plaintiff, DENNY L. TAYLOR, had implanted a Medtronic Sprint Fidelis Lead, Model No. 694965, Serial No. LFJ113862V.

69.61. On October 11, 2007, Plaintiff, GERALDINE MARIE TAYLOR-BROWN, had implanted a Medtronic Sprint Fidelis, Model No. 694965, Serial No. LFJ276196V.69.58.

69.62. On June 27, 2007, Plaintiff, KENNETH IAN TRAVIS, SR., had implanted a Medtronic Sprint Fidelis Lead, Model No. 693165ID, Serial No. LFL030862V.

69.63. On June 1, 2007, Plaintiff, LEONARD WENGROW, had implanted a Medtronic Sprint Fidelis Lead, Model No. 694965, Serial No. LFJ231803V.

69.64. On February 23, 2006, Plaintiff, ROBERT A. WILDER, had implanted a Medtronic Sprint Fidelis Lead, Model No. 694865ID, Serial No. LFH010383V.

69.65. On April 11, 2005, Plaintiff, RANDALL SCOTT WILLIAMS, had implanted a Medtronic Sprint Fidelis Lead, Model No. 694865ID, Serial No. LFH001899V.

69.66. On March 28, 2006, Plaintiff, DAVE WILSON, had implanted a Medtronic Sprint Fidelis,

Model No. 694965ID, Serial No. LFJ128887V.

- 70. Since implant of their Sprint Fidelis Leads, Plaintiffs have suffered from inappropriate and non-therapeutic shocks and/or failure of her implantable devices to deliver therapeutic shocks when warranted.
- 71. As a direct and proximate result of the acts and omissions of Defendants, Plaintiffs have suffered extreme physical injury and extreme emotional and psychological distress which includes an acute fear of sudden death. Plaintiffs continue to suffer from symptoms of heart palpitations, anxiety, and other debilitating injuries, which on information and belief will be permanent. They are under the constant care of their cardiologists, and suffer from post traumatic stress. Due to complications both physical and psychological suffered as result of the acts or omissions of Defendants, Plaintiffs have an increased risk of death or major cardiovascular events result. They have suffered medical expenses, lost income, and on information and belief, will suffer lost income and additional bills for treatment in the future. They will be required to pay others to perform services necessary for the ordinary tasks of everyday life. And because such acts or omissions were intentional, reckless, grossly negligent, willful and wanton, Plaintiffs pray for punitive damages in an amount commensurate with Defendants' culpability therefore.

VIII. CLAIMS FOR RELIEF

COUNT I

(STRICT LIABILITY-FAILURE TO WARN AND INSTRUCT)

- 72. Plaintiffs hereby incorporate by reference all preceding paragraphs as if fully set forth herein.
- 73. At all relevant times hereto, Defendants were engaged in the development, testing,

manufacturing, marketing and sales of Sprint Fidelis Leads. Defendants designed, manufactured, assembled and sold Sprint Fidelis Leads to medical professionals, knowing that they would then be implanted in patients with heart disease and disorders.

74. Defendants distributed and sold the Sprint Fidelis Leads in the condition in which they left their place of manufacture, in their original form of manufacture, which included the defects described herein. The Sprint Fidelis Leads were expected to and did reach Plaintiffs without substantial change or adjustment in their condition as manufactured and sold by Defendants.
75. The Sprint Fidelis Leads designed, developed, tested, manufactured, marketed and sold or otherwise placed into the stream of commerce by Defendants were in a dangerous and defective condition and posed a threat to any user or consumer of the Sprint Fidelis Leads. Plaintiffs were in a class of persons that Defendants should have considered to be subject to the harm caused by the defective nature of the Sprint Fidelis Leads.
76. The Sprint Fidelis Leads were implanted and used in the manner for which they were intended, that is for the detection, correction, and prevention of serious and/or life-threatening harm through surgical implantation. This use has resulted in injury to Plaintiffs.
77. Defendants knew or should have known through testing, adverse event reporting, or otherwise, that the Sprint Fidelis Leads created a high risk of bodily injury and serious harm.
78. Defendants failed to provide adequate and timely warnings or instructions regarding the Sprint Fidelis Leads and the known defects.
79. As a direct and proximate result of Defendants' wrongful conduct Plaintiffs have sustained and will continue to sustain severe physical injuries and/or increased risk of death, severe emotional distress, mental anguish, economic losses and other damages for which they are

entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

COUNT II

(STRICT LIABILITY-MANUFACTURING DEFECT)

80. Plaintiffs hereby incorporate by reference all preceding paragraphs as if fully set forth herein.
81. The Sprint Fidelis Leads are defectively manufactured because the foreseeable risks of mechanical malfunction and failure outweigh the benefits associated with the Sprint Fidelis Leads.
82. The Sprint Fidelis Leads were designed and/or manufactured in a manner violative of the Federal Food Drug and Cosmetic Act, 21 U.S.C. § 321 et seq., and the Medical Devices Amendment thereto (hereafter “FDCA”). The facilities or controls used by Defendants in the manufacture, packing, storage, or installation of the Sprint Fidelis Leads were not in conformity with applicable requirements of the FDCA.
83. The Sprint Fidelis Leads were expected to and did reach the Plaintiffs without substantial change or adjustment to their mechanical function upon implanting the Sprint Fidelis Leads.
84. Defendants knew or should have known of the manufacturing defects and the risk of serious bodily injury that exceeded the benefits associated with the Sprint Fidelis Leads.
85. Furthermore, the Sprint Fidelis Leads and their defects presented an unreasonably dangerous risk beyond what the ordinary consumer would reasonably expect.
86. The Sprint Fidelis Leads were defective due to inadequate warnings or instruction because Defendants knew or should have known that the Sprint Fidelis Leads created a high risk of bodily injury and serious harm. Defendants failed to adequately and timely warn consumers

of this risk.

87. The Sprint Fidelis Leads are inherently dangerous for their intended use due to manufacturing defect and improper functioning. Defendants are therefore strictly liable.
88. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs have sustained and will continue to sustain severe physical injuries and/or increased risk of death, severe emotional distress, mental anguish, economic losses and other damages for which they are entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

COUNT III

(NEGLIGENCE)

89. Plaintiffs hereby incorporate by reference all preceding paragraphs as if fully set forth herein.
90. At all relevant times, Defendants had a duty and continue to owe a duty to Plaintiffs to provide a safely manufactured product, to notify the FDA of flaws, and to warn the FDA and Plaintiffs of the defective nature of Sprint Fidelis Leads. Defendants breached their duty of reasonable care to Plaintiffs by incorporating a defect into the manufacture of the Sprint Fidelis Leads, thereby causing Plaintiffs' injuries.
91. Defendants breached their duty of reasonable care to Plaintiffs by manufacturing and assembling the Sprint Fidelis Leads in such a manner that they were prone to fray and/or fracture and fail to operate and malfunction and expose Plaintiffs to life-threatening physical trauma.
92. Defendants breached their duty of reasonable care to Plaintiffs by failing to promptly and adequately notify the FDA and warn, and instruct Plaintiffs, the medical community, and the

public at the earliest possible date of known defects in the Sprint Fidelis Leads.

- 93. Defendants breached their duty of reasonable care to Plaintiffs by failing to exercise due care under the circumstances.
- 94. As a direct and proximate result of Defendants' wrongful conduct Plaintiffs have sustained and will continue to sustain severe physical injuries and/or increased risk of death, severe emotional distress, mental anguish, economic losses and other damages for which they are entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

COUNT IV

(NEGLIGENCE PER SE)

- 95. Plaintiffs hereby incorporate by reference all preceding paragraphs as if fully set forth herein.
- 96. Defendants have an obligation not to violate the law in the manufacture, design, testing, assembly, inspection, labeling, packaging, supplying, marketing, selling, advertising, preparing for use, warning of the risks and dangers of the Sprint Fidelis Leads, and otherwise distributing the Sprint Fidelis Leads.
- 97. Defendants' acts constitute an adulteration, misbranding, or both, as defined by the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 331(a) and 333(a)(2), and constitute a breach of duty subjecting Defendants to civil liability for all damages arising there from, under theories of negligence per se.
- 98. Plaintiffs, as purchasers of Sprint Fidelis Leads, are within the class of persons the statutes and regulations (described above) are designed to protect and Plaintiffs' injuries are the type of harm these statutes and regulations are designed to prevent.

99. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs have sustained and will continue to sustain severe physical injuries and/or increased risk of death, severe emotional distress, mental anguish, economic losses and other damages for which they are entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

COUNT V

(BREACH OF IMPLIED WARRANTY)

100. Plaintiffs hereby incorporate by reference all preceding paragraphs as if fully set forth herein.
101. Defendants impliedly warranted that their Sprint Fidelis Leads, which Defendants designed, manufactured, assembled, promoted and sold to Plaintiffs, were merchantable and fit and safe for ordinary use.
102. Defendants further impliedly warranted that their Sprint Fidelis Leads, which Defendants designed, manufactured, assembled, promoted and sold to Plaintiffs, were fit for the particular purposes for which they were sold, including to provide prophylactic treatment of patients with prior myocardial infarction and a limited ejection fraction, patients who have had spontaneous and/or inducible life-threatening ventricular arrhythmia, and patients who are at high risk for developing such arrhythmia.
103. Contrary to these implied warranties, Sprint Fidelis Leads were defective, unmerchantable, and unfit for their ordinary use when sold, and unfit for the particular purpose for which they were sold.
104. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs have sustained and will continue to sustain severe physical injuries and/or increased risk of death, severe

emotional distress, mental anguish, economic losses and other damages for which they are entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

COUNT VI

(BREACH OF EXPRESS WARRANTY)

105. Plaintiffs hereby incorporate by reference all preceding paragraphs as if fully set forth herein.
106. Defendants expressly warranted to Plaintiffs by and through Defendants and/or their authorized agents or sales representatives, in publications, package inserts, the internet, and other communications intended for physicians, medical patients, and the general public, that the Sprint Fidelis Leads were safe, effective, fit and proper for their intended use.
107. In allowing the implantation of the Sprint Fidelis Leads, Plaintiffs and their physicians relied on the skill, judgment, representations, and express warranties of Defendants. These warranties and representations were false in that the Sprint Fidelis Leads were not safe and were, unfit for the uses for which they were intended.
108. Through sale of the Sprint Fidelis Leads, Defendants are merchants pursuant to Section 2-314 of the Uniform Commercial Code.
109. Defendants breached their warranty of the mechanical soundness of the Sprint Fidelis Leads by continuing sales and marketing campaigns highlighting the safety of its product, while they knew of the defects and risk of product failure.
110. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs have sustained and will continue to sustain severe physical injuries and/or increased risk of death, loss of companionship and society, severe emotional distress, mental anguish, economic losses and

other damages for which they are entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

COUNT VII

(NEGLIGENT MISREPRESENTATION)

111. Plaintiffs hereby incorporate by reference all preceding paragraphs as if fully set forth herein.
112. At the time Defendants manufactured, designed, marketed, sold and distributed the Sprint Fidelis Leads for use by Plaintiffs, Defendants knew or should have known of the use for which the Sprint Fidelis Leads were intended and the serious risks and dangers associated with such use of these Sprint Fidelis Leads.
113. Defendants owed a duty to treating physicians and ultimate end users of the Sprint Fidelis Leads, including Plaintiffs, to accurately and truthfully represent the risks of the Sprint Fidelis Leads. Defendants breached that duty by misrepresenting and/or failing to adequately warn Plaintiffs, the medical community and public about the risks of the Sprint Fidelis Leads, which Defendants knew or in the exercise of diligence should have known.
114. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs have sustained and will continue to sustain severe physical injuries and/or increased risk of death, severe emotional distress, mental anguish, economic losses and other damages for which they are entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

COUNT VIII

(INTENTIONAL MISREPRESENTATION)

115. Plaintiffs hereby incorporate by reference all preceding paragraphs as if fully set forth

herein.

116. Defendants, having undertaken to prepare, design, research, develop, manufacture, inspect, label, market, promote and sell the Sprint Fidelis Leads, owed a duty to provide accurate and complete information regarding the Sprint Fidelis Leads.
117. Defendants' advertising program and promotional items, by containing affirmative misrepresentations and omissions, falsely and deceptively sought to create the image and impression that the Sprint Fidelis Leads were safe for human use, had no unacceptable side effects and would not interfere with daily life.
118. Defendants purposefully concealed, failed to disclose, misstated, downplayed and understated the health hazards and risks associated with the use of the Sprint Fidelis Leads. Defendants, through promotional practices as well as the publication of medical literature, deceived potential treating physicians, Plaintiffs and the public. Defendants falsely and deceptively kept relevant information from potential treating physicians, the FDA and the general public, including Plaintiffs, regarding the safety of the Sprint Fidelis Leads.
119. Defendants expressly denied that the Sprint Fidelis Leads created an increased risk of injury and took affirmative steps to prevent the discovery and dissemination of any evidence on the increased likelihood of injury from the Sprint Fidelis Leads.
120. Defendants did not accurately report the results of adverse events by fraudulently and intentionally withholding information from the FDA, physicians, and the public, the truth regarding Sprint Fidelis Lead failures for months, if not years, all the while undertaking a major advertising campaign to sell products including the Sprint Fidelis Leads. Defendants received reports of the Sprint Fidelis defects from various sources, including Dr. Hauser, and intentionally withheld this information, while continuing to sell the Sprint Fidelis Leads for

implantation in individuals such as Plaintiffs.

121. Further, even as Defendants disclosed some information regarding the Sprint Fidelis defects, the disclosures were incomplete and misleading.
122. Defendants effectively deceived and misled the scientific and medical communities regarding the risks and benefits of the Sprint Fidelis Leads. The truth did not begin to emerge until, at the earliest, March 2007, when Medtronic issued a "Dear Doctor" letter to physicians that suggested that Sprint Fidelis defects were arising because of the manner in which the leads were being implanted. This letter was inadequate to fully inform physicians, patients, and the public of the true defects in the Sprint Fidelis Leads. Even after the letter, Defendants' sales representatives continued to assure physicians that Sprint Fidelis Leads were adequate and reliable for the purpose intended and continued to sell Sprint Fidelis Leads.
123. Through the materials they disseminated, Defendants falsely and deceptively misrepresented or omitted a number of material facts regarding the Sprint Fidelis Leads.
124. Defendants possessed evidence demonstrating the Sprint Fidelis Leads cause serious adverse side effects. Nevertheless, Defendants continued to market the Sprint Fidelis Leads by providing false and misleading information with regard to their safety to Plaintiffs and their treating physicians.
125. Defendants engaged in all the acts and omissions described above with the intent that Plaintiffs' physicians and Plaintiffs would rely on the misrepresentation, deception and concealment in deciding to use Defendants' Sprint Fidelis Leads.
126. Plaintiffs and their treating physicians justifiably relied to their detriment on Defendants' intentional and fraudulent misrepresentations as set out above. This reliance proximately

caused the injuries as damages detailed herein.

127. As a direct and proximate result of Defendants' wrongful conduct Plaintiffs have sustained and will continue to sustain severe physical injuries and/or increased risk of death, loss of companionship and society, severe emotional distress, mental anguish, economic losses and other damages for which they are entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

COUNT IX

(FRAUD)

128. Plaintiffs hereby incorporate by reference all preceding paragraphs as if fully set forth herein.
129. At all relevant times during the course of dealing between Defendants and Plaintiffs, Defendants misrepresented, omitted, and suppressed that the Sprint Fidelis Leads were not safe or effective for their intended use.
130. In representations to Plaintiffs, Defendants fraudulently concealed material information, specifically; that for several years, Defendants knew or had reason to know, of problems with their Sprint Fidelis Leads and that Sprint Fidelis Leads were defective, and that they were prone to fray or fracture, failed to operate and/or malfunctioned, and caused injuries and deaths.
131. Defendants also fraudulently concealed information regarding the Sprint Fidelis Lead defects from the FDA, preventing the FDA from performing its regulatory function.
132. Defendants were under a duty to disclose to Plaintiffs, the medical community, and public, the defective nature of the Sprint Fidelis Leads, and had full access to material facts concerning the defective nature of the Sprint Fidelis Leads and the propensity of the Sprint

Fidelis Leads to fray and/or fracture, and hence, cause injuries to the patients who had the Sprint Fidelis Leads implanted in them.

133. Defendants intentionally, knowingly, and/or recklessly misrepresented that the Sprint Fidelis Leads were safe and effective for their intended use even though Defendants knew as early as 2004 that fractures in the Sprint Fidelis Leads had occurred.
134. Defendants' misrepresentations, concealment, suppression and omissions were made purposefully, willfully, wantonly, uniformly, deliberately or recklessly to Plaintiffs; the medical community, and the public, to induce the purchase and use of Defendants' Sprint Fidelis Leads over other leads available on the market and to induce patients to agree to have the Sprint Fidelis Leads implanted into their bodies. Plaintiffs reasonably relied upon the misrepresentations and omissions made by the Defendants about the Sprint Fidelis Leads when agreeing to purchase and/or have the Sprint Fidelis Leads implanted into their bodies.
135. Defendants knew that Plaintiffs had no way to determine that the Defendants' representations about the Sprint Fidelis Leads were false and misleading, and that they included material omissions.
136. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs have sustained and will continue to sustain severe physical injuries and/or increased risk of death, severe emotional distress, mental anguish, economic losses and other damages for which they are entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

COUNT X

(CONSTRUCTIVE FRAUD)

137. Plaintiffs hereby incorporate by reference all preceding paragraphs as if fully set forth

herein.

138. At the time Defendants' sold the Sprint Fidelis Leads to Plaintiffs, Defendants were in a unique position of knowledge concerning the safety and effectiveness of the devices, which knowledge was not possessed by Plaintiffs or their physicians, and Defendants thereby held a position of superiority over Plaintiffs.
139. Through their unique knowledge and expertise regarding the defective nature of the Sprint Fidelis Leads, and through their statements to physicians and their patients in advertisements, promotional materials, and other communications, Defendants professed to Plaintiffs that they had knowledge of the truth of the representation that the Sprint Fidelis Leads were safe and effective for their intended use and were not defective.
140. Defendants' representations to Plaintiffs, the medical community, and public were unqualified statements made to induce Plaintiffs to purchase the Sprint Fidelis Leads, and Plaintiffs relied upon the statements when purchasing the devices and having them implanted in their bodies.
141. Defendants took unconscionable advantage of their dominant position of knowledge with regard to Plaintiffs and engaged in constructive fraud in their relationship with Plaintiffs. Plaintiffs reasonably relied on Defendants' representations.
142. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs have sustained and will continue to sustain severe physical injuries and/or increased risk of death, severe emotional distress, mental anguish, economic losses and other damages for which they are entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

COUNT XI

**(VIOLATION OF MINNESOTA FALSE STATEMENTS
IN ADVERTISING ACT)**

143. Plaintiffs hereby incorporate by reference all preceding paragraphs as if fully set forth herein.
144. Defendants produced and published advertisements and deceptive and misleading statements of the soundness and mechanical reliability of the Sprint Fidelis Leads after learning of their inherent defects with the intent to sell the Sprint Fidelis Leads.
145. Defendants concealed their deceptive practices in order to increase the sale of and profit from the Sprint Fidelis Leads.
146. Defendants violated the Minnesota False Statements in Advertising Act, Minn. Stat. § 325F.67 et seq., when they failed to comply with FDA requirements and when they failed to adequately warn consumers and the medical community of the safety risks associated with the Sprint Fidelis Leads.
147. Defendants violated Minn. Stat. § 325F.67 by intending to sell and create customer demand for the Sprint Fidelis Leads by using deceptive or untrue statements of fact about the Sprint Fidelis Leads' mechanical soundness and the reliability of the leads through promotional materials, including but not limited to, Defendants' website and medical brochures distributed to patients and physicians.
148. As a direct result of Defendants' deceptive, unfair, unconscionable, and fraudulent conduct and violation of Minn. Stat. § 325F.67 et seq., Plaintiffs were injured in that they paid substantial sums for the Sprint Fidelis Lead and/or for the costs of replacing the Sprint Fidelis Lead that they would not have paid had Defendants not engaged in unfair and deceptive conduct.

149. The Minnesota False Statement in Advertising Act applies to Plaintiffs' transactions with Defendants because Defendants' deceptive scheme was carried out in Minnesota and affected Plaintiffs implanted with the defective Sprint Fidelis Leads.
150. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs have also sustained and will continue to sustain severe physical injuries and/or increased risk of death, loss of companionship and society, severe emotional distress, mental anguish, economic losses and other damages for which they are entitled to statutory, compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

COUNT XII

(VIOLATION OF THE MINNESOTA DECEPTIVE TRADE PRACTICE ACT)

151. Plaintiffs hereby incorporate by reference all preceding paragraphs as if fully set forth herein.
152. Defendants applied advertising and marketing campaigns representing the Sprint Fidelis Leads as mechanically sound and medically safe, while Defendants knew of the defects in the Sprint Fidelis Leads. Defendants continued these campaigns of deception until 2007, when the Sprint Fidelis Leads were recalled.
153. Defendants knew or should have known of the defective nature of the Sprint Fidelis Leads but denied public access to the information, to avoid corporate responsibility. Defendants knew the Plaintiffs and their physicians were at a disadvantage in accessing information involving the safety of the Sprint Fidelis Leads.
154. Defendants concealed the defects of the Sprint Fidelis Leads for the purposes of higher profits and increased sales.
155. Defendants have violated Minn. Stat. § 325D.44. The violations include the following:

- a. Defendants violated Minn. Stat. § 325D.44(5) by representing the Sprint Fidelis Leads as having characteristics, uses, and benefits of a safe and mechanically sound device while knowing the statements were false and the Sprint Fidelis Leads contained inherent defects, including manufacturing defects;
- b. Defendants violated Minn. Stat. § 325D.44(7) by representing the Sprint Fidelis Leads as a non-defective medical product of a particular standard, quality, or grade while knowing the statements were false and the Sprint Fidelis Leads contained inherent defects, including manufacturing defects;
- c. Defendants violated Minn. Stat. § 325D.44 (9) by advertising, marketing, and selling the Sprint Fidelis Leads as medically reliable and without a known design defect while knowing those claims were false and without any medical support; and
- d. Defendants violated Minn. Stat. § 325D.44(13) by creating a likelihood of confusion about the efficacy and mechanical soundness of the Sprint Fidelis Leads, comparing the Sprint Fidelis Leads with other non-defective products.

156. The Minnesota statutes prohibiting unfair and deceptive trade practices apply because Defendants' deceptive scheme was carried out in Minnesota and affected Plaintiffs who were implanted with the Sprint Fidelis Lead containing the known defects.

157. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs have sustained and will continue to sustain severe physical injuries and/or increased risk of death, loss of companionship and society, severe emotional distress, mental anguish, economic losses and other damages for which they are entitled to statutory, compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

COUNT XIII

**(VIOLATION OF THE MINNESOTA PREVENTION OF
CONSUMER FRAUD ACT)**

158. Plaintiffs hereby incorporate by reference all preceding paragraphs as if fully set forth herein.
159. Defendants intentionally concealed their design and manufacturing defects and failed to disclose the defects for the purpose of continuing to sell and distribute the Sprint Fidelis Leads.
160. Defendants represented that the Sprint Fidelis Leads were safe and effective and intended that Plaintiffs and their physicians rely on those representations when deciding if Defendants' Sprint Fidelis Leads were optimal for meeting the Plaintiffs' needs.
161. Through these misleading and deceptive statements and false promises, Defendants violated Minn. Stat. § 325F.69.
162. The Minnesota statutes prohibiting consumer fraud apply to all of Defendants' transactions with Plaintiffs who were implanted with the Sprint Fidelis Leads because Defendants' deceptive scheme was carried out in Minnesota and affected Plaintiffs who were implanted with a defective Sprint Fidelis Lead.
163. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs have sustained and will continue to sustain severe physical injuries and/or increased risk of death, severe emotional distress, mental anguish, economic losses and other damages for which they are entitled to statutory, compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

COUNT XIV

(VIOLATION OF THE SENIOR CITIZEN AND HANDICAPPED PERSON

CONSUMER FRAUD ACT-MINN. STAT. § 325F.71)

164. Plaintiffs hereby incorporate by reference all preceding paragraphs as if fully set forth herein.
165. Pursuant to Minn. Stat. § 325F.71(2), this Count applies to Plaintiffs who may be Senior Citizens or Handicapped, as defined within the statute.
166. Minn. Stat. § 325F.71(2) incorporates the afore-referenced Minnesota Statutes 325D.43 to 325D.48 regarding deceptive trade practices, 325F.67 regarding false advertising and 325F.68-70 regarding consumer fraud and provides special remedies if violations of those statutes are directed against Senior Citizens or handicapped people, including priority of restitution 325F.71(3) and the recovery of “damages, including costs of investigation and reasonable attorney’s fees” and to “other equitable relief as determined by the Court.” 325F.71(4).
167. The affirmative misrepresentations and the pattern of omissions by Defendants described above, violated Minn. Stat. § 325F.44, Subd. 1, (5) because, through those affirmative misrepresentations and the pattern of omissions, Defendants represented that the Sprint Fidelis Leads had “characteristics, ingredients, uses [and/or] benefits . . . that they do not have. . . ,” a per se violation of Minn. Stat. § 325F.71.
168. The affirmative misrepresentations and the pattern of omissions by Defendants described above, violated Minn. Stat. § 325F.44, Subd. 1, (6).
169. The affirmative misrepresentations and the pattern of omissions by Defendant described above, violated Minn. Stat. § 325F.44, Subd. 1, (7) because, through those affirmative misrepresentations and the pattern of omissions, Defendants represented that the Sprint Fidelis Leads were of a “particular standard, quality or grade. . . ,” when they were, in fact,

of a much lower standard, quality or grade, a per se violation of Minn. Stat. § 325F.71.

170. The affirmative misrepresentations and the pattern of omissions by Defendants in their Annual Reports, advertising literature, press releases and other public statements, constitutes false advertising as prohibited by Minn. Stat. § 325F.67, a per se violation of Minn. Stat. § 325F.71.
171. The conduct, affirmative misrepresentations and the pattern of omissions by Defendant described above constitutes a “fraud, false pretense, false promise, misrepresentation, misleading statement or deceptive practice, with the intent that others rely thereon in connection with the sale of . . . [the Sprint Fidelis Leads],” in violation of Minn. Stat. § 325F.69, Subd. 1, a per se violation of Minn. Stat. § 325F.71.
172. Pursuant to Minn. Stat. § 325F.71, Subd. 4, Plaintiffs are entitled to recover all damages arising out of Defendants’ violation of Minn. Stat. § 325F.44, Subd. 1, (5), (6) and/or (7); Minn. Stat. § 325F.67 and/or Minn. Stat. § 325F.69, Subd. 1.
173. As a direct and proximate result of Defendants’ wrongful conduct Plaintiffs have sustained and will continue to sustain severe physical injuries and/or increased risk of death, loss of consortium, severe emotional distress, mental anguish, economic losses and other damages for which they are entitled to statutory, compensatory and equitable damages and declaratory relief in an amount to be proven at trial.
174. In addition, Plaintiffs are entitled to recover costs of investigation and reasonable attorney’s fees pursuant to Minn. Stat. § 325F.71, Subd. 4, and Plaintiffs respectfully request that the Court give priority to the remedy of “restitution” pursuant to Minn. Stat. § 325F.71, Subd. 3.

COUNT XV

(NEGLIGENT INFILCTION OF EMOTIONAL DISTRESS)

175. Plaintiffs hereby incorporate by reference all preceding paragraphs as if fully set forth herein.
176. Defendants carelessly and negligently manufactured, marketed and sold the Sprint Fidelis Leads to Plaintiffs, carelessly and negligently concealed the Sprint Fidelis defects from Plaintiffs, and carelessly and negligently misrepresented the quality, safety and usefulness of the Sprint Fidelis Leads.
177. Plaintiffs were directly involved in and directly impacted by Defendants' carelessness and negligence, in that Plaintiffs sustained severe physical injuries and/or increased risk of death, economic losses, and other damages as a direct result of the decision to purchase, use and have implanted in their bodies a defective and dangerous product manufactured, sold and distributed by Defendants.
178. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs have sustained and will continue to sustain severe physical injuries and/or increased risk of death, severe emotional distress, mental anguish, economic losses and other damages for which they are entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

COUNT XVI

(INTENTIONAL INFILCTION OF EMOTIONAL DISTRESS)

179. Plaintiffs hereby incorporate by reference all preceding paragraphs as if fully set forth herein.
180. Medtronic engaged in extreme and outrageous conduct, knowingly and/or recklessly marketing defective Leads, knowingly and/or recklessly concealing a known and potentially

fatal defect from Plaintiffs, and knowingly and/or recklessly misrepresenting the quality and usefulness of the Sprint Fidelis Leads.

181. As a direct result of Medtronic's misconduct, Plaintiffs sustained physical injuries, economic losses and other damages.
182. Medtronic intended to cause Plaintiffs severe emotional distress, or acted with reckless disregard for Plaintiffs' emotional state.
183. Plaintiffs were directly involved in and directly impacted by Defendants' extreme and outrageous conduct, in that Plaintiffs sustained severe physical injuries and/or increased risk of death, economic losses, and other damages as a direct result of the decision to purchase, use and has implanted in their bodies a defective and dangerous product manufactured, sold and distributed by Defendants.
184. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs have sustained and will continue to sustain severe physical injuries and/or increased risk of death, severe emotional distress, mental anguish, economic losses and other damages for which they are entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

COUNT XVII

(UNJUST ENRICHMENT)

185. Plaintiffs hereby incorporate by reference all preceding paragraphs as if fully set forth herein.
186. As the intended and expected result of their conscious wrongdoing, Defendants have profited and benefitted from the purchase of Defendants' Sprint Fidelis Lead by Plaintiffs.
187. Defendants have voluntarily accepted and retained these profits and benefits, derived from

the Plaintiffs, with the knowledge and awareness that, as a result of Defendants' fraud and other conscious and intentional wrongdoing, Plaintiffs were not receiving a product of the quality, nature or fitness that had been represented by Defendants or that Plaintiffs, as reasonable consumers, expected.

188. By virtue of the conscious wrongdoing alleged above, Defendants have been unjustly enriched at the expense of the Plaintiffs, who are entitled to in equity, and hereby seek, the disgorgement and restitution of Defendants' wrongful profits, revenues and benefits, to the extent and in the amount deemed appropriate by the Court; and such other relief as the Court deems just and proper to remedy the Defendants' unjust enrichment.

COUNT XVIII

(MEDICAL MONITORING)

189. Plaintiffs hereby incorporate by reference all preceding paragraphs as if fully set forth herein.
190. Through the unlawful conduct set forth in the preceding paragraphs, Plaintiffs have been implanted with a device which tends to fracture, and otherwise malfunction. These defects have potentially fatal consequences for many patients who rely upon the presence of the leads connected to the ICDs to regulate their cardiac rhythms.
191. As a direct and proximate result of the conduct of Defendants outlined above, Plaintiffs implanted with the recalled Sprint Fidelis Lead have suffered physical injuries including but not necessarily limited to death, emergency and additional surgeries to remove or otherwise replace fractured leads, implantation of additional leads and devices in addition to the leads, excessive and or inappropriate shocking, and various physical manifestations of emotional distress associated with one or more of the following; the implantation, recall, failure,

removal/replacement, and/or inability to have the defective Sprint Fidelis Lead removed or replaced.

192. As a direct and proximate result of the conduct of Defendants outlined above, Plaintiffs who have not yet had their most recently implanted Sprint Fidelis Lead removed or replaced, or who is unable to have their recalled Sprint Fidelis Lead removed or replaced, have also been exposed to greater risks of severe injury, including lead fracture and death.
193. As set forth above, the now recalled Sprint Fidelis Leads have a greater propensity to fracture than other leads available on the market. Thus, these Plaintiffs have been exposed to an even greater risk of additional and serious injury.
194. As set forth above, the now recalled Sprint Fidelis Leads are defective and dangerous such that they were the subject of a Class I Recall. Class I Recalls are the most serious type of medical device recall and involve situations in which there is a reasonable probability that the use of the produce will cause serious injury or death.
195. Plaintiffs' increased risk of additional and serious injury is a direct and proximate result of Defendants' negligence and liability as set forth above.
196. As set forth above, the monitoring procedures currently recommended by Medtronic do not adequately detect potential fractures in the Sprint Fidelis Lead wires and more aggressive medical monitoring can and should be implemented for early detection of potential fractures.
197. In the absence of exposure to a now recalled Sprint Fidelis Lead, Plaintiffs would not be at the increased risk of additional and serious injury. Plaintiffs would also not be forced to expend additional monies and incur additional economic damages for such monitoring.
198. As a direct and proximate result of Defendants' negligence and liability, a more aggressive monitoring regime is reasonably necessary and supported by contemporary scientific

principles.

199. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs have sustained and will continue to sustain severe physical injuries and/or increased risk of death, severe emotional distress and physical manifestations thereof, mental anguish, economic losses and other damages for which they are entitled to compensatory and equitable damages and declaratory relief in amounts to be proven at trial, including but not limited to the establishment of a treatment fund, under the continuing jurisdiction and supervision of this Court, to monitor the health of Plaintiffs, and to pay or reimburse Plaintiffs for all evaluative, monitoring, diagnostic, preventative, and corrective medical, surgical, and incidental expenses caused by Medtronic's wrongdoing and declaratory judgment that Medtronic is liable to Plaintiffs for all evaluative, monitoring, diagnostic, preventative, and corrective medical, surgical, and incidental expenses, costs and losses caused by Medtronic's wrongdoing.

COUNT XIX

(MEDICARE SECONDARY PAYER ACT)

200. Plaintiffs hereby incorporate by reference all preceding paragraphs as if fully set forth herein.

201. In addition to their own personal injury claims, Plaintiffs, whose medical care costs arising from the Sprint Fidelis Lead were paid in whole or in part by Medicare, bring this cause of action pursuant to the private cause of action provisions of the Medicare as Secondary Payer Statute [42 U.S.C. § 1395y(b)(3)(A)] ("MSP") to recover "double damages" of all Medicare expenditures resulting from their injuries suffered in connection with the Recalled Medtronic Sprint Fidelis Leads.

COUNT XX

(VIOLATION OF STATE CONSUMER PROTECTION STATUTES)

202. Plaintiffs hereby incorporate by reference all preceding paragraphs as if fully set forth herein.
203. Defendants have a statutory duty to refrain from unfair or deceptive acts or practices in the design, development, manufacture, promotion and sale of the defective leads.
204. Had the Defendants not engaged in the deceptive conduct described above, Plaintiffs would not have purchased and/or paid for the defective leads, and would not have incurred related medical costs.
205. Defendants' deceptive, unconscionable or fraudulent representations and material omissions to patients, physicians and consumers, including Plaintiffs, constituted unfair and deceptive acts and practices in violation of the state consumer protection statutes listed below:
 - a. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 6 Del. Code § 2511, et seq. and 2531, et seq.;
 - b. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Fla. Stat. § 501.201, et seq.;
 - c. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ga. Stat. § 10-1-372, et seq., 10-1-392 and 10-1-420.
 - d. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Haw. Rev. Stat. § 480-1, et seq.;
 - e. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Tex. Bus. & Com. Code § 17.41, et seq.
206. Defendants engaged in wrongful conduct while at the same time obtaining, under false

pretenses, substantial sums of money from Plaintiffs for the defective leads that they would not have paid had Defendants not engaged in unfair and deceptive conduct.

207. Defendants' actions, as complained of herein, constitute unfair competition or unfair, unconscionable, deceptive or fraudulent acts or practices in violation of state consumer protection statutes, as listed below:
 - a. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 6 Del. Code § 2511, et seq. and 2531, et seq.;
 - b. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Fla. Stat. § 501.201, et seq.;
 - c. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ga. Stat. § 10-1-372, et seq., 10-1-392 and 10-1-420.
 - d. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Haw. Rev. Stat. § 480-1, et seq.;
 - e. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Tex. Bus. & Com. Code § 17.41, et seq.
208. Plaintiffs were injured by the cumulative and indivisible nature of Defendants' conduct. The cumulative effect of Defendants' conduct directed at patients, physicians and consumers was to create demand for and sell the defective leads. Each aspect of Defendants' conduct combined to artificially create sales of the defective leads.
209. The medical community relied upon Defendants' misrepresentations and omissions in determining which cardiac device to utilize.
210. By reason of the unlawful acts engaged in by Defendants, Plaintiffs have suffered ascertainable loss and damages.

211. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs were damaged by paying in whole or in part for these defective leads.
212. As a direct and proximate result of Defendants' violations of Plaintiffs' state consumer protection statutes, Plaintiffs have sustained economic losses and other damages for which they are entitled to statutory, compensatory damages and declaratory relief in an amount to be proven at trial. Defendants are liable to Plaintiffs jointly and severally for all general, special and injunctive relief to which she is entitled by law. Under statutes enacted in all the states and District of Columbia to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising, Plaintiffs are consumers who purchased Medtronics' Sprint Fidelis leads pursuant to a consumer transaction for personal use and is therefore subject to protection under such legislation.
213. Under statutes enacted in all the states and the District of Columbia to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising, Medtronic is the supplier, manufacturer, advertiser, and seller, who is subject to liability under such legislation for unfair, deceptive, fraudulent and unconscionable consumer sales practices.
214. Defendants violated the statutes enacted in all the states and the District of Columbia to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising, by knowingly and falsely representing that the leads were fit to be used for the purpose for which they were intended, when in fact the leads were defective and dangerous, and by other acts alleged herein. These representations were made in uniform promotional materials.
215. The actions and omissions of Defendants alleged herein are uncured or incurable deceptive

acts under the statutes enacted in all the states and the District of Columbia to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising.

216. Defendants had actual knowledge of the defective and dangerous condition of the Sprint Fidelis leads, and failed to take any action to cure such defective and dangerous conditions.

IX. PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for judgment against Defendants as follows:

- a. Economic and non-economic damages in an amount in excess of \$75,000 as provided by law and to be supported by the evidence at trial;
- b. For the equitable relief requested;
- c. For compensatory damages according to proof;
- d. For all applicable statutory damages under the Medicare Secondary Payer Act;
- e. For all applicable statutory damages under the consumer protection legislation of the states of Delaware, Florida, Georgia, Hawaii, Texas and Minnesota;
- f. For declaratory judgment that Defendants are liable to Plaintiffs for all evaluative, monitoring, diagnostic, preventative, and corrective medical, surgical, and incidental expenses, costs and losses caused by Defendants' wrongdoing;
- g. For disgorgement of profits;
- h. For an award of attorneys' fees and costs;
- i. For prejudgment interest and the costs of suit; and
- j. For such other and further relief as this Court may deem just and proper.

X. JURY DEMAND

Plaintiffs hereby demand a trial by jury in this case as to such issues so triable.

Dated: August 18, 2009.

Respectfully submitted,

David W. Alexander

David W. Alexander
Texas Bar No. 24029417
USDC SDTX Bar No. 32900
John T. Boundas
Texas Bar No. 00793367
USDC SDTX Bar No. 25155
James L. Doyle II
Texas Bar No. 06094450
USDC SDTX Bar No. 10576

WILLIAMS KHERKHER HART BOUNDAS, LLP
8441 Gulf Freeway, Ste. 600
Houston, Texas 77017
Telephone: (713) 230-2200
Facsimile: (713) 643-6226